

Appln No. 10/040,932

Amdt date October 9, 2003

Reply to Office action of June 9, 2003

REMARKS/ARGUMENTS

Claims 1 to 4, 9 to 17, 19, 20 and 22 to 28 are pending in this application, of which claim 1 is independent. Claims 1, 2, 9, 19, 20 and 22 through 25 have been amended. Claims 5 to 8, 18 and 21 have been canceled. The amendments add no new matter and find full support in the application as originally filed. In view of the above amendments and following remarks, Applicant respectfully requests reconsideration and a timely indication of allowance.

Rejections Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 2, 4, 10 to 12 and 26 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ben Haim (U.S. Patent No. 6,574,492). The Examiner has also rejected claims 1, 2, 4, 10 to 13 and 26 under 35 U.S.C. §102(b) as allegedly being anticipated by Ben Haim (U.S. Patent No. 6,285,898). Claims 2, 4, 10 to 13 and 26 each depend from claim 1.

Applicant has amended claim 1 to recite that each spine comprises a support arm having shape memory; a non-conductive covering in surrounding relation to the support arm; at least one location sensor mounted in the distal end of the spine; a tip electrode mounted on the distal end of the spine and electrically isolated from the support arm; at least two ring electrodes mounted in surrounding relation to the non-conductive cover, and a plurality of electrode lead wires extending within the non-conductive covering, each electrode lead wire being attached to a corresponding one of the tip electrode and ring electrodes. Such a design is neither taught nor suggested by either of the Ben Haim patents.

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Ben Haim '492 in FIG. 14A, cited by the Examiner, discloses a catheter having a covering (312) including a resilient cap member (320) extending distally from the catheter and comprising an elastomeric material. The cap member includes a tuft of distally extending resilient lobes (322). At least one sensor (332) is fixed to the resilient cap member. Ben Haim '492 does not teach or suggest the claimed support arm having shape memory within the cap member or the inclusion of electrodes on the cap member. Ben Haim '898 in FIG. 10, cited by the Examiner, discloses a multi-head catheter, each head having a position sensor. (See column 22, lines 32 to 36.) The Examiner cites to column 23, lines 1 to 9, which describes a preferred embodiment in which at least one electrode (79) is preferably mounted at tip (74) in addition to the position sensor (76). This discussion does not appear to relate to the multi-head catheter, as the reference numerals in this discussion are not included in FIG. 10, but are included in the normal (i.e., single-head) version of the catheter depicted in FIG. 6. Moreover, Ben Haim '898 does not teach or suggest the inclusion of a support arm having shape memory disposed within a non-conductive covering as presently claimed. Accordingly, claim 1 is novel and unobvious over the two claimed. Ben Haim patents, and Applicant requests that the rejections under section 102(b) be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 2, 4, 5, 7, 10, 11 and 26 to 28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hummel (U.S. Patent No. 5,551,426) in view of Ben-Haim '492; claim 3 as allegedly being unpatentable over Ben-

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Haim '492 or Ben-Haim '898 in further view of Ponzi (U.S. Patent No. 6,374,476); claims 3 and 6 as allegedly being unpatentable over Hummel in view of Ben-Haim '492 in further view of Ponzi; claims 8, 9 14 to 19 and 21 to 23 under 35 as allegedly being unpatentable over Hummel in view of Ben-Haim '492 and in further view of Webster, Jr. (U.S. Patent No. 5,411,025); claims 12 and 13 as allegedly being unpatentable over Hummel in view of Ben-Haim '492 in further view of Tu (U.S. Patent No. 6,231,570); claim 20 as allegedly being unpatentable over Hummel in view of Ben-Haim '492 and Webster in further view of Ponzi; and claims 24 and 25 as allegedly being unpatentable over Hummel in view of Ben-Haim '492 and Webster and in further view of Tu. Applicant respectfully traverses these rejections. Claims 5, 7, 8, 18 and 21 have been cancelled.

Hummel is directed to an ablation and mapping catheter having a plurality of preformed wires 6 each having an enamel coating 16 over most of its length with an exposed J-shaped distal end that is used as an electrode. Each of Hummel's preformed wires 6 is essentially an electrode lead wire having the enamel coating removed from its distal end, which is then shaped in the form of the letter "J." However, Hummel does not disclose a support arm having shape memory extending through a non-conductive coating with a tip electrode that is electrically isolated from the support arm, as presently claimed. Ben Haim '492 does not make up for this deficiency. Accordingly, the combination of Hummel and Ben Haim '492 does not render obvious the claimed combination.

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The Examiner states that Webster Jr. teaches the particular structure of the spines that is missing from Hummel and Ben Haim. Applicant respectfully submits that there is insufficient motivation to combine Webster with Hummel and/or Ben Haim to arrive at the claimed invention.

Webster discloses a catheter having a basket-shaped electrode assembly at its distal end. The basket assembly includes a plurality of arms (9) connected to each other at their proximal and distal ends. Each arm has an outer tube (18) of a flexible insulating material supported by a flexible spine (25) made of Nitinol. The spines are joined at their proximal and distal ends by proximal and distal fittings (12 and 14), respectively. The fittings hold the arms in proper angular orientation with respect to each other, thus maintaining the proper spacing of the arms and the proper orientation of the basket. This is important because the catheter is subjected to a pumping heart wall and must also be rotated during the mapping process. (See column 6, lines 27 to 37.) Also, the fittings and support arms permit the user to open and close the basket assembly. Thus, the support arms disclosed in Webster are critical to the functioning of the basket.

Webster provides no motivation to include such support arms in the designs of Ben Haim '492 and Hummel, where the distal ends of the spines are free (i.e., not connected to each other or anything else). Webster describes no purpose for such arms other than for proper manipulation of the basket assembly and to maintain the relative spacing of the arms of the baskets. Such concerns are not at issue in Ben Haim '492 and Hummel. As such,

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one skilled in the art would not look to the design of Webster's basket-shaped assembly to modify the spines of Ben Haim '492 and/or Hummel. Applicant therefore respectfully submits that even the combination of Hummel, Ben Haim '492 and Webster does not render obvious the claimed combination.

The Examiner states that Ponzi teaches the particular structure of the location sensor mounted within the tip electrode. Ponzi discloses a catheter with a single deflectable tip section mounted to a catheter body. The tip section includes a puller wire 42 for deflecting the tip. Ponzi provides no motivation for including a mapping assembly mounted at the distal end of the catheter body as currently claimed. In addition, Ponzi does not disclose "at least two spines, each spine having a proximal end attached at the distal end of the catheter body and a free distal end, wherein each spine comprises: a support arm having shape memory." Hence Ponzi does not make up for the deficiencies in Ben-Haim '492, Ben-Haim 898, Hummel and Webster. As such, even the combination of any of Ben-Haim '492, Ben-Haim 898, Hummel, Webster and Ponzi does not render the claimed invention obvious.

The Examiner states that Tu teaches the particular radial direction of the spines upon displacement. Tu teaches an electrode catheter assembly having a plurality of inner micro-catheters 11. Upon actuation by a deployment means 9, the inner micro-catheters 11 extend from a distal end 3 of a delivery catheter 1 and, due to the preformed shape of the inner micro-catheters 11, the inner micro-catheters 11 extend outwardly and radially of the delivery catheter 1 when deployed. However,

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even though the inner micro-catheters 11 each have a preformed shape, they do not include "a support arm having shape memory" and a "non-conductive covering in surrounding relation to the support arm" as recited in the present claims. Hence Tu does not make up for the deficiencies of Ben-Haim '492, Ben-Haim 898, Hummel, Webster and Ponzi. As such, even the combination of any of Ben-Haim '492, Ben-Haim 898, Hummel, Webster, Ponzi and Tu does not render the claimed invention obvious.

Accordingly, the claimed invention is novel and unobvious over the combination of any of Ben-Haim '492, Ben-Haim 898, Hummel, Webster, Ponzi and Tu, and Applicant requests that the rejections under section 103(a) be withdrawn

In view of the above amendments and remarks, Applicant respectfully submits that claims 1 to 4, 9 to 20 and 22 to 28 are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number indicated.

Respectfully submitted,
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